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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,311	12/12/2005	Meena Augustus	357074.00006	4638

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Saul Ewing LLP (Baltimore)
Attn: Patent Docket Clerk
Penn National Insurance Plaza
2 North Second Street, 7th Floor
Harrisburg, PA 17101

EXAMINER

KIM, YOUNG J

ART UNIT	PAPER NUMBER
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1637

MAIL DATE	DELIVERY MODE
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02/17/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/540,311	Applicant(s) AUGUSTUS ET AL.	
	Examiner Young J. Kim	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-18, 28-30, 67 and 69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16 and 28-30 is/are rejected.
- 7) ☒ Claim(s) 17, 18, 67 and 68 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The present Office Action is responsive to the After-Final Amendment received on December 30, 2010.

The present Office Communication contains at least one rejection which is not necessitated by Amendment and thus, the prosecution of the case has been hereby re-opened, and the finality of the last Office Action, withdrawn.

Preliminary Remark

The after-final amendment received on December 30, 2010 has been entered.

Consequently, claims 1-15, 19-27, 31-66, 68, and 70 have been canceled.

Claims 16-18, 28-30, and 67 are pending and are under prosecution herein.

Claim Rejections - 35 USC § 112

The rejection of claims 16-18, 65, 67, and 68 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, made in the Office Action mailed on August 5, 2010 is withdraw in view of the Amendment received on December 30, 2010.

The scope of enablement rejection of claims 16-18, 28-30, and 69 under 35 U.S.C. 112, first paragraph, made in the Office Action mailed on August 5, 2010 is withdrawn in view of the Amendment received on December 30, 2010.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 16 and 28-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is indefinite for reciting the phrase, "determining a cell copy number of at least one gene..." It is unclear whether the phrase is stating that the cell copy number is being determined or the copy number of the at least one gene is being determined. Since Applicants' amendment appears to have been made based on the Examiner's suggestion, the latter interpretation has been assumed.

Claim 28 is indefinite for the recitation of the phrase, "detecting in a sample from a patient expression of a gene ... wherein said expression is increased the copy number of said gene."

The phrase does not make grammatical sense. Additionally, the determination of a copy number of gene is different from "expression" of the gene (*i.e.*, transcription level).

Claims 29 and 30 are indefinite by way of their dependency.

Examiner's Comment

Instantly claimed nucleic acid of SEQ ID NO: 1 is disclosed as encoding the protein of SEQ ID NO 7.

According to the instant specification, SEQ ID Number 1 is a cDNA of the gene, TRIP13, which is disclosed as being increased in both gene copy number as well as transcriptionally over-expressed:

"In accordance with the present invention, a gene, called TRIP13 (Thyroid hormone Receptor Interacting Protein), has been identified that is both amplified and transcriptionally over-expressed in tumor cells but not in otherwise normal tissues." (page 2, line 31 to page 3, line 3)

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Baak et al. (WO 02/10436 A2, issued February 7, 2002, of record) disclose a protein which is 100% identical to instant SEQ ID NO: 7, wherein the artisan disclose that this protein is over-expressed in breast cancer samples (see claim 1).

Baak et al., however, do not disclose that the number of gene copies encoding the protein is increased in breast cancer samples.

Sutherland et al. (Acta Oncologica, 1995, vol. 34, no. 5, pages 651-656) evidences that not all genes which are amplified results in increased expression of the gene products:

“Increased expression of cyclin D1 was the most common alteration in cyclin gene expression noted in these cell lines. This gene was highly expressed in MDA-MB-134, -175, -330, and -453 cells and one of two MCF-7 variants, Compared with the level of mRNA observed in the majority of the breast cancer cell lines and in two strains of normal, non-transformed breast epithelial cells ... Cyclin D1 **gene amplification was detected in six cell lines but amplification was not a prerequisite for, and did not always lead to, increased cyclin D1 expression.**” (page 654, 2nd column, bottom paragraph).

Therefore, one of ordinary skill in the art would **not have had a reasonable expectation of success** at concluding that the cause of the increased protein level determined by Baak et al. was based on the increased copy number of the gene encoding that protein.

Since there was no reasonable expectation of success, there would also have been no motivation to arrive at the claimed invention based on the disclosure of Baak et al.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 6:00 a.m. to 2:30 p.m (M-F). The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Young J. Kim/
Primary Examiner
Art Unit 1637
2/16/2011

/YJK/